(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 January 2002 (24.01.2002)

PCT

(10) International Publication Number
WO 02/05731 A1

(51) International Patent Classification[7]: A61F 2/06

(21) International Application Number: PCT/US01/22725

(22) International Filing Date: 18 July 2001 (18.07.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/219,040 18 July 2000 (18.07.2000) US

(71) Applicant and
(72) Inventor: **TEITELBAUM, George, P.** [US/US]; 325 16th Street, Santa Monica, CA 90402-2217 (US).

(74) Agents: **FARAH, David, A.** et al.; Sheldon & Mak, 225 South Lake Avenue, 9th Floor, Pasadena, CA 91101 (US).

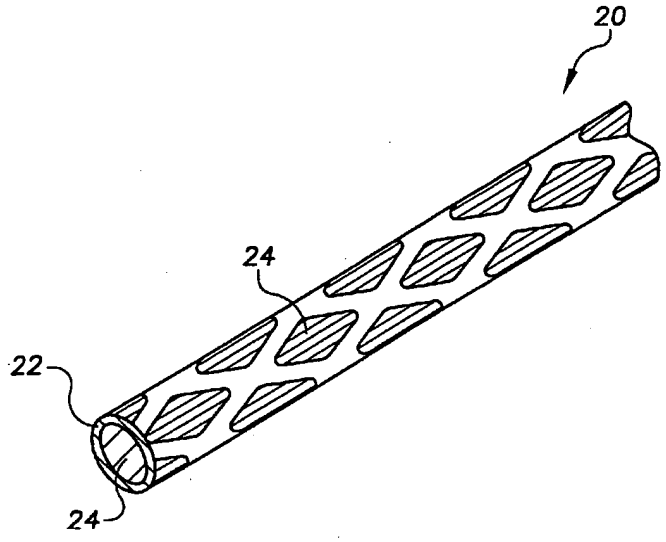
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: BIOCOMPATIBLE, EXPANSILE MATERIAL AND STENT



(57) Abstract: A biocompatible, expansile material (10) suitable for implantation into the body of an animal, including a human, comprising two outer layers (12) of semipermeable substance and a central layer (14) of hydrophillic substance between the two outer layers (12), where water passing through the two outer layers (12) of semipermeable substance is absorbed by the central layer (14) causing the material to expand.

WO 02/05731 A1

BIOCOMPATIBLE, EXPANSILE MATERIAL AND STENT

CROSS-REFERENCE TO RELATED APPLICATIONS

The present Application clams the benefit of United States patent application 60/219,040 titled "Expansile Graft Material," filed July 18, 2000, the contents of which are incorporated herein by reference in its entirety.

BACKGROUND

There are a variety of surgical procedures that require the implantation of medical devices that expand after implantation. For example, coronary angioplasty is frequently followed by stent implantation in the coronary artery. The stent is implanted in a collapsed form and expanded at the desired site by a variety of methods. Other expandable medical devices, such as coils, are also used to occlude the lumen of blood vessels and to occlude the lumen of vascular aneurysms.

It is advantageous to have a material Tanya Hall can be used to produce stents with as low a profile as possible to allow placement in the largest number of arteries. Further, it is advantageous to have material that can be used to produce a stent in a variety of complex shapes.

Therefore, it would be useful to have a material that can be used to make medical devices that expand after implantation in an animal or human. Further, it would be useful to have medical devices, such as stents and coils, that can expand after implantation in an animal or human. Additionally, it would be useful to have a material that can be used to produce a stent with as low a profile. Further, it would be useful to have a material that can be used to produce a stent in a variety of complex shapes.

SUMMARY

According to one embodiment of the present invention, there is provided a biocompatible, expansile material suitable for implantation into the body of an animal, including a human. The material comprises two outer layers of semipermeable substance, and a central layer of hydrophillic substance between the two outer layers. Water passing through the two outer layers of semipermeable substance is absorbed by the central layer causing the material to expand.

In one embodiment, the one or more than one of the two outer layers comprises material selected from the group consisting of polytetrafluoroethylene, polyurethane and

dacron. In another embodiment of the present invention, the one or more than one of the two outer layers comprises microscopic pores or a plurality of slits that allow water to pass through the outer layer. In a preferred embodiment, the central layer comprises collagen or comprises agar. Preferably, the expansion of the material increases the thickness from about 10% to about 600%.

According to another embodiment of the present invention, there is provided a biocompatible, expansile material suitable for implantation into the body of an animal, including a human. The material comprises a outer layer of semipermeable substance and a central core of hydrophillic substance surrounded by the outer layer. Water passing through the outer layer of semipermeable substance is absorbed by the central core causing the material to expand.

In one embodiment, the outer layer comprises a material selected from the group consisting of polytetrafluoroethylene, polyurethane and dacron. In another embodiment of the present invention, the outer layer comprises microscopic pores or a plurality of slits that allow water to pass through the outer layer. In a preferred embodiment, the central layer comprises collagen or comprises agar. Preferably, the expansion of the material increases the thickness from about 10% to about 600%.

In a preferred embodiment of the present invention, there is provided a biocompatible, expansile material suitable for implantation into the body of an animal, including a human. The material comprises a reinforcing wire surrounded by an outer coil of the material according to the present invention. In a preferred embodiment, the reinforcing wire comprises a substance selected from the group consisting of nitinol, platinum, tungsten, and combinations of platinum, tungsten and nitinol. In a preferred embodiment, the reinforcing wire has a diameter of between about 0.15 mm and about 1 mm.

According to another embodiment of the present invention, there is provided a biocompatible, expansile material suitable for implantation into the body of an animal, including a human. The material comprising sheets of laterally connected longitudinally arranged linear lengths of a material according to the present invention.

According to another embodiment of the present invention, there is provided a biocompatible, expansile stent suitable for implantation into the body of an animal, including a human. The stent comprises a proximal end and a distal end, and a generally tubular structure made of laterally interconnected, longitudinally arranged linear lengths of the

material according to the present invention between the proximal end and distal end. In a preferred embodiment, the lateral interconnections are reinforced, such as with polytetrafluoroethylene. In a particularly preferred embodiment, the proximal end and distal end have a larger diameter than the portion of the stent between the proximal end and the distal end.

According to yet another embodiment of the present invention, there is provided a method for effecting patency, maintaining patency or both, of a tubular structure within the body of an animal or human. The method comprises the steps of first, selecting an animal or human having a tubular structure suitable for insertion of a sent according to the present invention. Next, a delivery catheter containing a stent is advanced into the tubular structure to the site of intended placement of the stent. Then, the stent is placed into the tubular structure and allowing the stent to assume an appropriate shape. The stent is allowed to absorb water from the within the tubular structure and expand. In a particularly preferred embodiment, the tubular structure in the selected animal or human is a coronary artery. In another embodiment, the delivery catheter is removed from the tubular structure.

FIGURES

These and other features, aspects and advantages of the present invention will become better understood with regard to the following description, appended claims, and accompanying figures where:

Figure 1 is a top perspective view of a sheet of material according to one embodiment of the present invention before expansion of the material;

Figure 2 is a top perspective view of a sheet of material shown in Figure 1 after expansion of the material;

Figure 3 is a top perspective view of a sheet of material according to another embodiment of the present invention before expansion of the material;

Figure 4 is a top perspective view of a sheet of material shown in Figure 3 after expansion of the material;

Figure 5 is a top perspective view of a suture made of material according to one embodiment of the present invention expansion of the material;

Figure 6 is a top perspective view of a suture made of material shown in Figure 5, after expansion of the material;

Figure 7 is a top perspective, partial cutaway view of another material according to

one embodiment of the present invention before expansion of the material;

Figure 8 is a top perspective, partial cutaway view of the material shown in Figure 7, after expansion of the material;

Figure 9 is a lateral, cross-sectional view of an artery adjacent an aneurysm with a coil of the material according to the present invention placed in the artery adjacent the neck of the aneurysm, before expansion of the material;

Figure 10 is a lateral, cross-sectional view of an artery adjacent an aneurysm with a coil of the material according to the present invention placed in the artery adjacent the neck of the aneurysm, after expansion of the material;

Figure 11 is a lateral, cross-sectional view of an artery adjacent an aneurysm with a coil of the material according to the present invention placed in the aneurysm, before expansion of the material;

Figure 12 is a lateral, cross-sectional view of an artery adjacent an aneurysm with a coil of the material according to the present invention placed in the aneurysm, after expansion of the material;

Figure 13 is a top perspective view of another embodiment of the material shown in Figure 7, before implantation;

Figure 14 is a top perspective view of another embodiment of the material shown in Figure 7, after implantation;

Figure 15 is lateral perspective view of a stent according to one embodiment of the present invention after placement in a tubular structure but before expansion;

Figure 16 is a lateral perspective view of the stent shown in Figure 15 after placement is a tubular structure and after expansion;

Figure 17 is a lateral perspective view of a stent according to another embodiment of the present invention;

Figure 18 is a lateral perspective, cross-sectional view of a tubular structure during delivery of a stent according to the present invention into the tubular structure from a delivery catheter;

Figure 19 is a lateral perspective, cross-sectional view of the tubular structure shown in Figure 18 after delivery of the stent but before expansion of the stent; and

Figure 20 is a lateral perspective, cross-sectional view of the tubular structure shown in Figure 18 after delivery of the stent and after expansion of the stent.

DESCRIPTION

According to one embodiment of the present invention, there are provided biocompatible, expansile materials suitable for implantation into the body of an animal, including a human. According to another embodiment of the present invention, there are provided biocompatible, expansile medical devices suitable for implantation into the body of an animal, including a human. Examples of expansile medical devices include vascular stents, biliary stents, and esophageal stents. According to yet another embodiment of the present invention, there are provided methods of implanting the material or devices of the present invention into the body of an animal, including a human. The materials, devices and methods will now be discussed in detail.

Referring now to Figure 1 and to Figure 2, there are shown, respectively, a top perspective view of a sheet of material according to one embodiment of the present invention, before expansion, and a top perspective view of a sheet of material shown in Figure 1, after expansion. Referring now to Figure 3 and to Figure 4, there are shown, respectively, a top perspective view of a sheet of material according to another embodiment of the present invention, before expansion, and a top perspective view of a sheet of material shown in Figure 3, after expansion. As can be seen, the material 10 comprises two outer layers of semipermeable substance 12 surrounding a central layer 14 of hydrophillic substance. Each outer layer 12 comprises one or more than one biocompatible substance that substantially allows water to pass through the substance. Preferably, the substance is biocompatible, stable *in vivo*, easily formed into sheets or shapes, and sterilizable. In a preferred embodiment, each outer layer 12 comprises polytetrafluoroethylene (PTFE). However, other substances are also suitable, such as polyurethane or dacron, as will be understood by those in the art with reference to this disclosure.

Each outer layer 12 can be formed of a sheet, or can be formed in other shapes. Preferably, the each outer layer 12 comprises microscopic pores 16 that allow water to pass through, as shown in Figure 1 and Figure 2. Alternately, or coincidentally, each outer layer 12 can comprise a plurality of slits 18, as shown in Figure 3 and Figure 4, to allow greater expansion of the material 10 as a whole.

The central layer 14 comprises one or more than one hydrophillic substance that is biocompatible, stable *in vivo*, easily formed into sheets or shapes, and sterilizable. Additionally, the hydrophillic substance absorbs water and expands upon absorbing water. In

a preferred embodiment, the central layer 14 comprises collagen or comprises agar, a natural hydrocolloid polymer of subunits of galactose extracted from seaweed. However, other substances are also suitable, as will be understood by those in the art with reference to this disclosure.

The material 10 in manufactured by co-extrusion as will be understood by those with skill in the art with reference to this disclosure. Additionally, the pores 16 or slits 18 can be created by laser cutting.

Once the material 10 is implanted into an animal, water passes through each outer layer 12 and is absorbed by the central layer 14, causing the central layer 14 to expand, and increasing in thickness from about 10% to about 600%. Expansion of the central layer 14 expands the implanted material 10, as can be seen in Figure 2 and Figure 4. Preferably, the expansion continues over hours to days rather than seconds, in order to allow the surrounding tissues to adapt to the increasing size of the material 10 gradually, and to allow implantation of the material 10 while the material 10 is in the unexpanded state.

Referring now to Figure 5 and Figure 6, there are shown, respectively, a top perspective view of another material according to one embodiment of the present invention before expansion, and a top perspective view of the material shown in Figure 5, after expansion. The material can be used for a variety of purposes, such as sutures. As can be seen, the material 20 comprises an outer layer of semipermeable substance 22 surrounding a central core 24 of hydrophillic substance. The outer layer 22 comprises one or more than one biocompatible substance that substantially allows water to pass through the substance. Preferably, the substance is biocompatible, stable *in vivo*, easily formed into tubes, and sterilizable. In a preferred embodiment, the outer layer 22 comprises polytetrafluoroethylene. However, other substances are also suitable, such as polyurethane or dacron, as will be understood by those in the art with reference to this disclosure.

The outer layer 22 can be formed of a tube having microscopic pores (not shown). However, as shown in Figure 5 and Figure 6, the outer layer 22 preferably comprises a plurality of slits 26 to allow greater expansion of the material 20 as a whole.

The central core 24 comprises one or more than one hydrophillic substance that is biocompatible, stable *in vivo*, easily formed into cylinders, and sterilizable. Additionally, the hydrophillic substance absorbs water and expands upon absorbing water. In a preferred embodiment, the central core 24 comprises collagen or comprises agar. However, other

substances are also suitable, as will be understood by those in the art with reference to this disclosure.

The material 20 is manufactured by co-extrusion as will be understood by those with skill in the art with reference to this disclosure. Additionally, the slits 26 can be created by laser cutting.

Once the material 20 is implanted into an animal, water passes through the outer layer 22 and is absorbed by the central core 24, causing the central core 24 to expand, and increasing in thickness from about 10% to about 600%. Expansion of the central core 24 expands the material 20, as can be seen in Figure 5 and Figure 6. Preferably, the expansion continues over hours to days rather than seconds, in order to allow the surrounding tissues to adapt to the increasing size of the material 20 gradually, and to allow implantation of the material 20 while the material 20 is in the unexpanded state.

Referring now to Figure 7 and Figure 8, there are shown, respectively, a top perspective, partial cutaway view of another material according to one embodiment of the present invention before expansion, and a top perspective, partial cutaway view of the material shown in Figure 7, after expansion. As can be seen, the material 30 comprises a reinforcing wire 32 surrounded by an outer coil of the material 20, according to the present invention. The ends of the reinforcing wire 32 are depicted in the figures as being not covered by the material 20 purely for illustration purposes, but would be covered by the material 20 when actually being used.

The reinforcing wire 32 comprises one or more than substance that is biocompatible, stable *in vivo*, easily formed into wires, and sterilizable. In a preferred embodiment, the reinforcing wire 32 comprises nitinol, which is a nickel, titanium, oxygen and carbon alloy. In a preferred embodiment, the reinforcing wire has a diameter of between about 0.15 mm and about 1 mm, though other gauges are suitable depending on the intended use, as will be understood by those in the art with reference to this disclosure. However, other substances are also suitable, such as platinum, tungsten, and combinations of platinum, tungsten or nitinol, as will be understood by those in the art with reference to this disclosure.

The material 30 in manufactured by production of the material 20, and then, by wrapping the material 20 around the reinforcing wire 32, according to techniques known to those with skill in the art.

Once the material 30 is implanted into an animal, water passes through the outer layer

22 or the material 20 and is absorbed by the central core 24, causing the central core 24 to expand, and increasing in thickness from about 10% to about 600%. Preferably, the expanding continues over hours to days rather than seconds, in order to allow the surrounding tissues to adapt to the increasing size of the material 30 gradually, and to allow implantation of the material 30 while the material 30 is in the unexpanded state.

The reinforcing wire 32 allows the material 30 to be produced in a variety of shapes, such as a coil, and allows the material 30 to maintain the shape during and after expansion of the material 30. For example, a coil of the material 30 can be used to occlude a blood vessel or other conduit within the body of an animal, or to occlude an aneurysm or an arteriovenous malformation or fistula.

Referring now to Figure 9 and Figure 10, there are shown a lateral, cross-sectional view of an artery 100 adjacent an aneurysm 102 with a coil of the material 30 according to the present invention placed in the artery 100 adjacent the neck of the aneurysm 102, before expansion of the material 30, Figure 9, and after expansion of the material 30, Figure 10. As can be seen, expansion of the material 30 occludes the lumen of the artery 100 adjacent the neck of the aneurysm 102, preventing rupture of the aneurysm 102.

Referring now to Figure 11 and Figure 12, there are shown, respectively, a lateral, cross-sectional view of an artery 100 adjacent an aneurysm 102 with a coil of the material 30 according to the present invention placed in the aneurysm, before expansion of the material 30, and after expansion of the material 30. As can be seen, expansion of the material 30 occludes the lumen of the aneurysm 102, preventing rupture of the aneurysm 102.

Referring now to Figure 13 and Figure 14, there are shown, respectively, a top perspective view of another embodiment of the material 30 of the present invention before expansion, and a top perspective view of the material 30 shown in Figure 13, after expansion. As can be seen, the material 30 is formed into sheets of laterally interconnected, longitudinally arranged linear lengths of the material 30. Before implantation, the linear lengths of the material 30 are loosely arranged. After implantation, the linear lengths of the material 30 expand and can be configured to expand sufficiently to create a water tight sheet of material 30.

According to another embodiment of the present invention, there is provided a stent suitable for use implantation in a tubular structure of an animal, such as a coronary artery in a human, in order to effect patency, maintain patency or both, of the tubular structure.

Referring now to Figure 15 and Figure 16, there are shown, respectively, lateral perspective views of a stent according to one embodiment of the present invention after placement in the tubular structure but before expansion, and after expansion. As can be seen, the stent 40 comprises a proximal end 42 and a distal end 44. Between the proximal end 42 and distal end 44, the stent 40 comprises a generally tubular structure made of laterally connected longitudinally arranged linear lengths of the material 20 according to the present invention, or more preferably the material 30. Each interconnection 46 can be reinforced, as shown, such as, for example, with polytetrafluoroethylene or using suture material.

Referring now to Figure 17, there is shown a lateral perspective view of a stent 40 according to another embodiment of the present invention. In this embodiment the proximal end 42 and distal end 44 have a larger diameter than the portion of the stent 40 between the proximal end 42 and the distal end 44.

Referring now to Figure 18, Figure 19 and Figure 20, there are shown lateral perspective, cross-sectional views of a tubular structure 104 during delivery of the stent 40 according to the present invention into the tubular structure 104 from a delivery catheter 106, Figure 18, and after delivery of the stent 40 but before expansion of the stent 40, Figure 19, and after delivery of the stent 40 and after expansion of the stent, Figure 20.

According to another embodiment of the present invention, there is provided a method for effecting patency, maintaining patency or both, of a tubular structure within the body of an animal or human. The method comprises, first selecting an animal or human having a tubular structure suitable for insertion of a sent according to the present invention. For example, the tubular structure can be a coronary artery and the human selected can be undergoing angioplasty to treat decreased patency of the coronary artery. Next, a delivery catheter containing a stent according to the present invention can be placed into the tubular structure and advanced to the site of intended placement of the stent. Then, the stent is placed into the tubular structure and allow to assume an appropriate shape. The delivery catheter is removed. Finally, the material comprising the stent absorbs water from the within the tubular structure and expands.

Although the present invention has been discussed in considerable detail with reference to certain preferred embodiments, other embodiments are possible. Therefore, the scope of the appended claims should not be limited to the description of preferred embodiments contained in this disclosure.

I CLAIM:

1. A biocompatible, expansile material suitable for implantation into the body of an animal, including a human, the material comprising:

a) two outer layers of semipermeable substance; and

b) a central layer of hydrophillic substance between the two outer layers; and

where water passing through the two outer layers of semipermeable substance is absorbed by the central layer causing the material to expand.

2. The material of claim 1, where one or more than one of the two outer layers comprises material selected from the group consisting of polytetrafluoroethylene, polyurethane and dacron.

3. The material of claim 1, where one or more than one of the two outer layers comprises microscopic pores that allow water to pass through the outer layer.

4. The material of claim 1, where one or more than one of the two outer layers comprises a plurality of slits.

5. The material of claim 1, where the central layer comprises collagen or comprises agar.

6. The material of claim 1, where expansion of the material increases in thickness from about 10% to about 600%.

7. A biocompatible, expansile material suitable for implantation into the body of an animal, including a human, the material comprising:

a) a outer layer of semipermeable substance; and

b) a central core of hydrophillic substance surrounded by the outer layer; and

where water passing through the outer layer of semipermeable substance is absorbed by the central core causing the material to expand.

8. The material of claim 7, where the outer layer comprises a material selected from the group consisting of polytetrafluoroethylene, polyurethane and dacron.

9. The material of claim 7, where the outer layer comprises microscopic pores that allow water to pass through the outer layer.

10. The material of claim 7, where the outer layer comprises a plurality of slits.

11. The material of claim 7, where the central core comprises collagen or comprises agar.

12. The material of claim 7, where expansion of the material increases in thickness

from about 10% to about 600%.

13. A biocompatible, expansile material suitable for implantation into the body of an animal, including a human, the material comprising a reinforcing wire surrounded by an outer coil of the material of claim 7.

14. The material of claim 13, where the reinforcing wire comprises a substance selected from the group consisting of nitinol, platinum, tungsten, and combinations of platinum, tungsten and nitinol.

15. The material of claim 13, where the reinforcing wire has a diameter of between about 0.15 mm and about 1 mm.

16. A biocompatible, expansile material suitable for implantation into the body of an animal, including a human, the material comprising sheets of laterally connected longitudinally arranged linear lengths of the material of claim 13.

17. A biocompatible, expansile stent suitable for implantation into the body of an animal, including a human, the stent comprising:

a) a proximal end and a distal end; and

b) a generally tubular structure made of laterally interconnected, longitudinally arranged linear lengths of the material of claim 13 between the proximal end and distal end.

18. The stent of claim 17, where the lateral interconnections are reinforced.

19. The stent of claim 17, where the reinforcements comprise polytetrafluoroethylene.

20. The stent of claim 17, where the proximal end and distal end have a larger diameter than the portion of the stent between the proximal end and the distal end.

21. A method for effecting patency, maintaining patency or both, of a tubular structure within the body of an animal or human, comprising the steps of:

a) selecting an animal or human having a tubular structure suitable for insertion of a sent according to claim 17;

b) advancing a delivery catheter containing a stent into the tubular structure to the site of intended placement of the stent;

c) placing the stent into the tubular structure and allowing the stent to assume an appropriate shape; and

d) allowing the stent to absorb water from the within the tubular structure and expand.

22. The method of claim 21, where the tubular structure in the selected animal or

human is a coronary artery.

23. The method of claim 21, further comprising removing the delivery catheter from the tubular structure.

FIG. 1

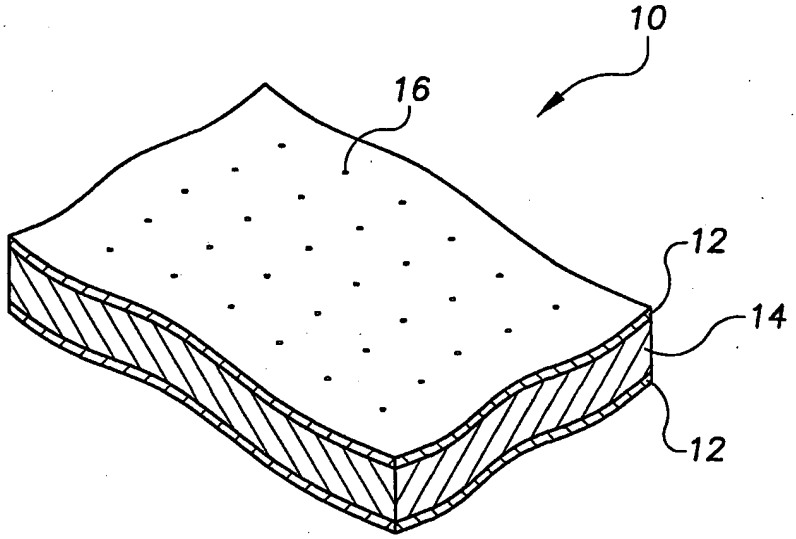


FIG. 2

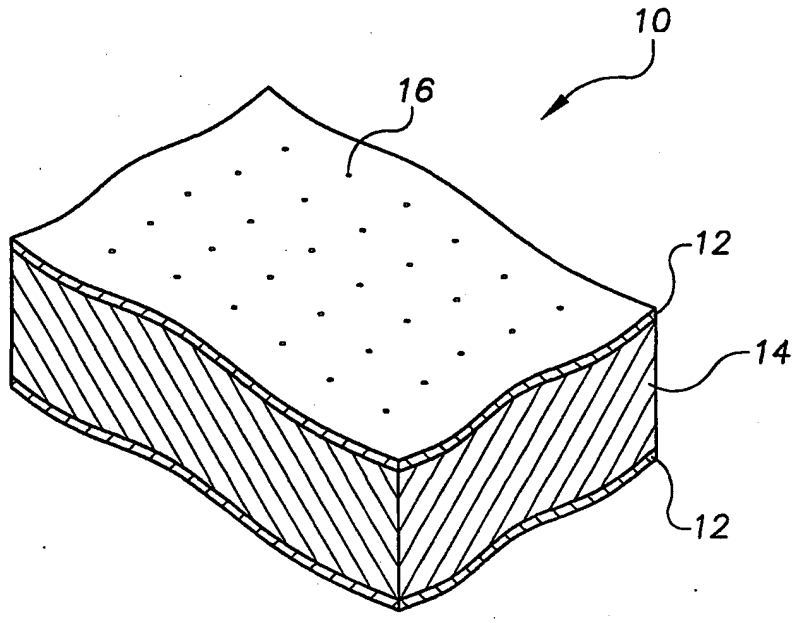


FIG.3

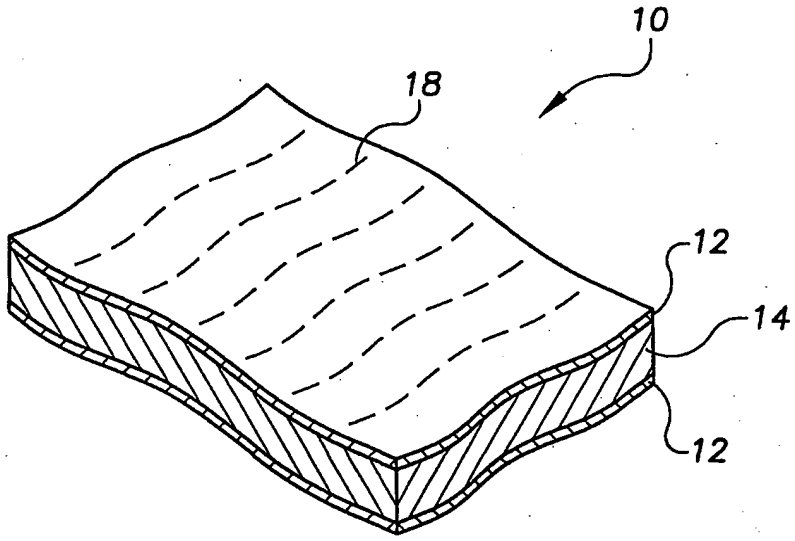


FIG.4

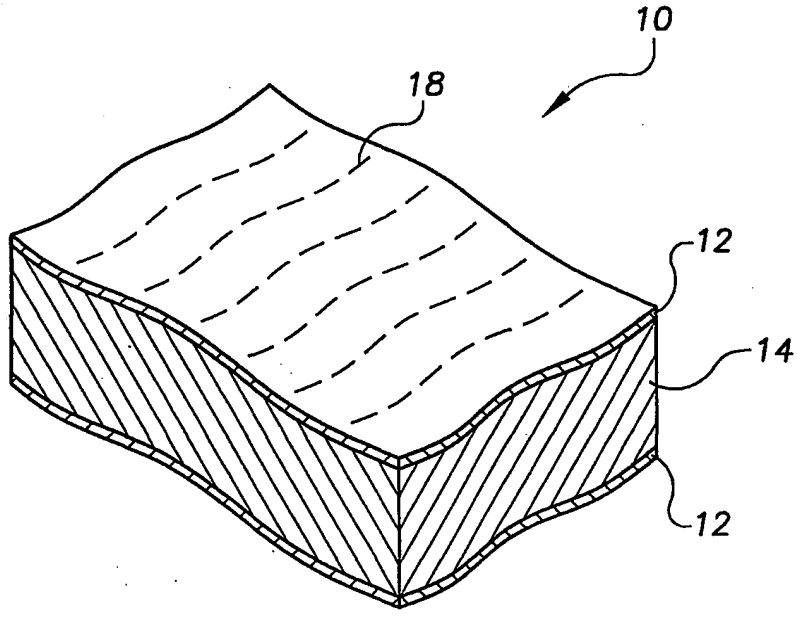


FIG.5

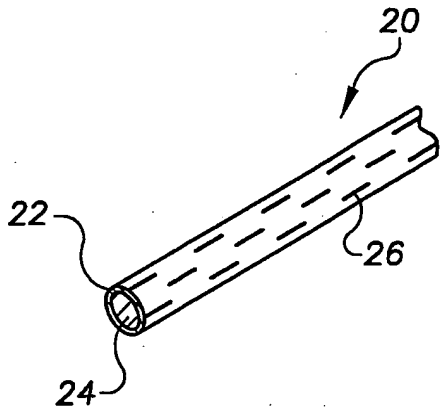


FIG.6

FIG.7

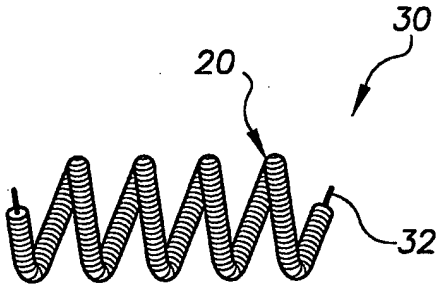


FIG.8

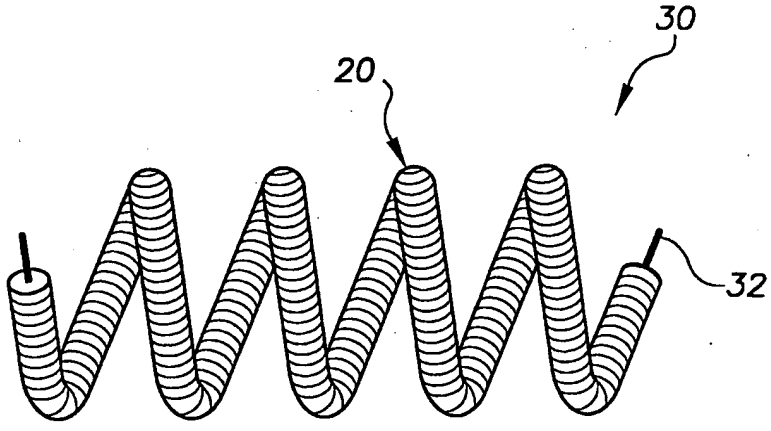


FIG. 9

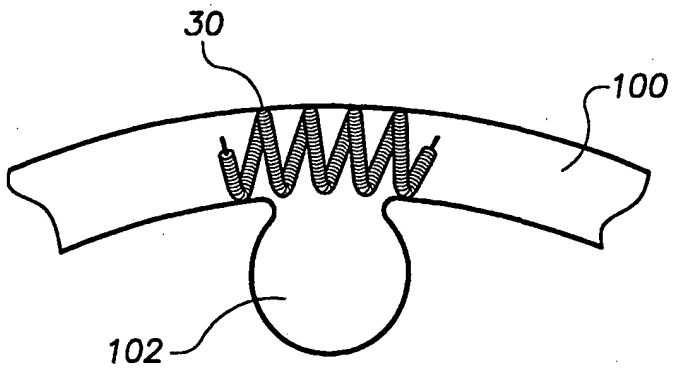


FIG. 10

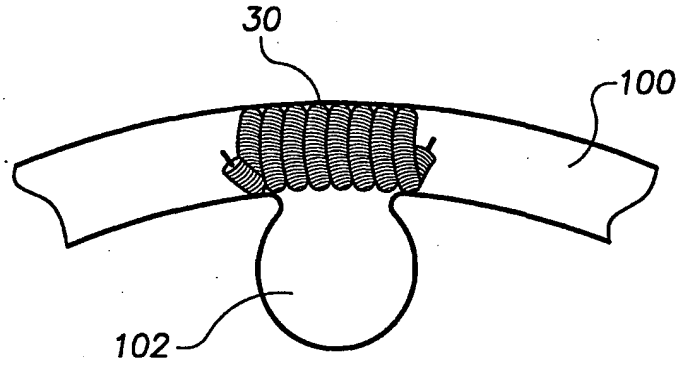


FIG. 11

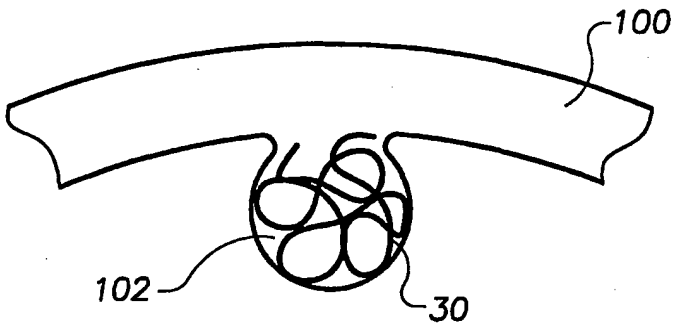


FIG. 12

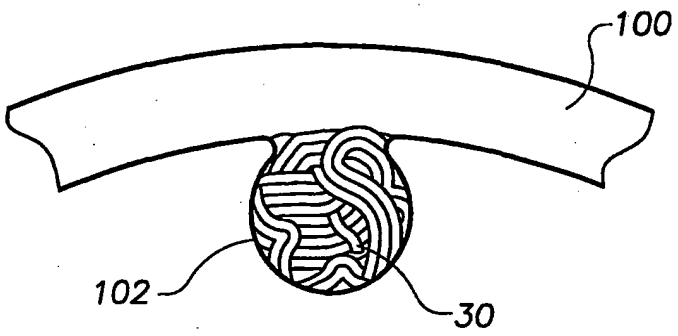


FIG. 13

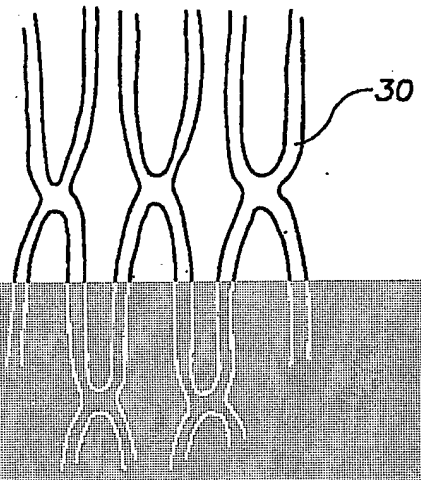


FIG. 14

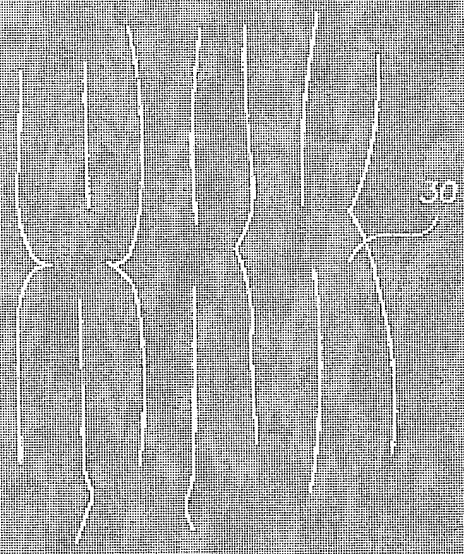


FIG. 15

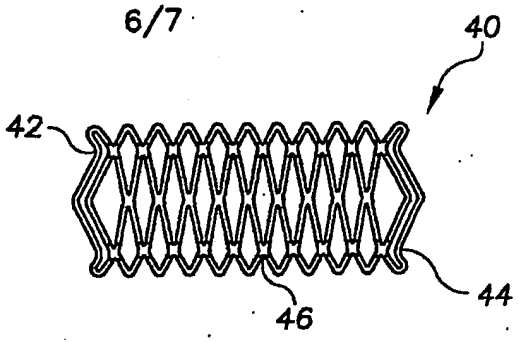


FIG. 16

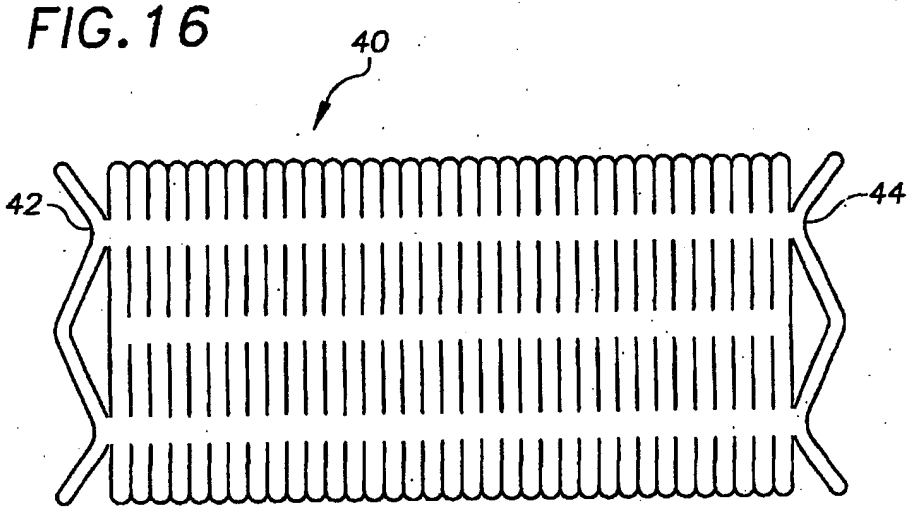


FIG. 17

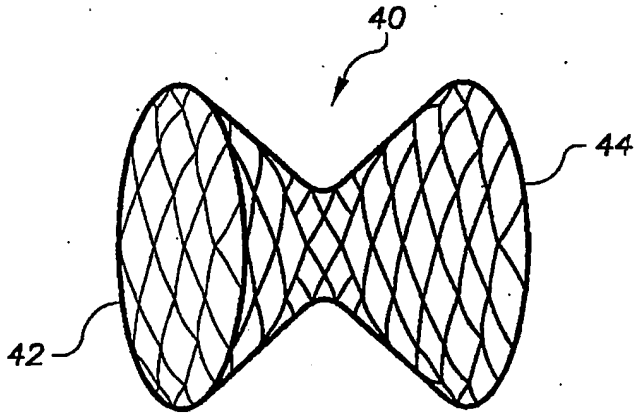


FIG. 18

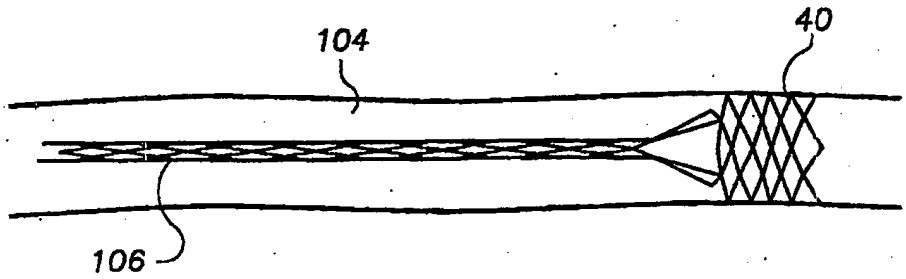


FIG. 19

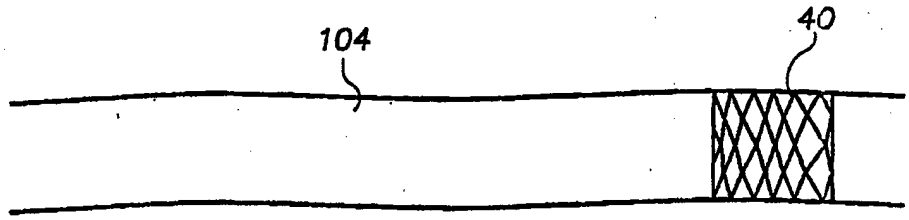
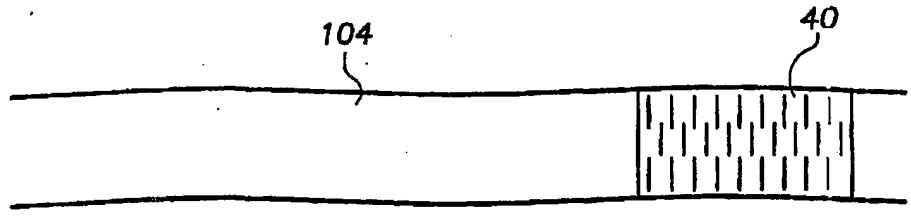


FIG. 20



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/22725

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 2/06
US CL :623/1.44
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1.44-1.48; 604/368, 378

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST BRS
search terms: layer, collagen, ptfe, stent, agar, platinum

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,735,897 A (BUIRGE) 07 April 1998, see entire document.	1-4,7-10 --- 5,6,11
Y	US 5,554,180 A (TURK) 10 September 1996, see entire document.	5,11
X,P --- Y,P	US 6,117,168 A (YANG et al.) 12 September 2000, see entire document.	7-11 --- 1-6,12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
22 SEPTEMBER 2001	27 DEC 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JULIAN W. WOO Telephone No. (703) 308-0421

Form PCT/ISA/210 (second sheet) (July 1998)*